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TAGS: [ECON](#) [ETRD](#) [KIPR](#) [SI](#)
SUBJECT: SLOVENIA: 2009 SPECIAL 301 REVIEW - RECOMMEND
AGAINST WATCHLIST INCLUSION

REF: A. SECSTATE 8401
[1](#)B. 08 LJUBLJANA 81
[1](#)C. 07 LJUBLJANA 103
[1](#)D. 06 LJUBLJANA 119
[1](#)E. 05 LJUBLJANA 127

Summary

[1](#)1. (SBU) Post recommends that Slovenia continue to not be included on the Special 301 watch list. Slovenian legislation on intellectual property rights (IPR) and data protection is fully aligned with EU legislation, TRIPS, WIPO, and other ratified international treaties. The Government of Slovenia, however, has yet to implement the EU Transparency Directive. In practice, U.S. pharmaceutical companies have access to the Slovene market. 2008 efforts by the former Government of Slovenia (GoS) to balance the health-care budget, curb inflation, and reduce government spending, posed some problems for "innovative" drug producers. But the GoS has been responsive to commercial concerns. The Ministry of Health's MoH incorporation of the Pharmaceutical Research and Manufacturers of America (PhRMA) and Post's pricing concerns in the pricing regulation implemented in 2007 and the omission of the therapeutic reference pricing from the Medicine Act submitted by the MoH in February 2008 are both positive signs. As well as working with PhRMA to address its concerns, over the last few years, Post has been cooperating with the GoS to provide training for judges, prosecutors, and staff at the Slovenian Intellectual Property Office to help address the challenges of the overburdened courts and strengthen U.S.-EU cooperation of IPR protection. In September, Slovenia held elections and a new Government was sworn in in November 2008. PhRMA has informed us that it is lobbying the new government and is waiting to see the new government's position. Post believes GoS cooperation will continue to increase, and recommends that Slovenia not be included on the Special 301 Watch List. END SUMMARY.

PhRMA's Special 301 Submission

[1](#)2. (SBU) PhRMA's Special 301 Submission highlights the Slovenian MoH pricing policies and reimbursement programs. The most serious complaint is that: "Slovenia was required to implement the provisions of the European Union's Transparency Directive governing pricing and reimbursement of pharmaceuticals regulation by the end of June 2008, but has failed to do so." Although Post has not received a response from the GoS on this point, the government has since changed, and Post believes it would be unfair and unwise to penalize the new government for failings of the last regime. PhRMA had asked Post to advocate on their behalf on pricing issues with the prior government. However, PhRMA representatives told EmbOffs in January 2009, that they were in the process of negotiating with the new MoH and did not want Embassy advocacy at that point. Post interprets this as a positive sign that PhRMA has a more cooperative relationship with the

current GoS.

¶3. (SBU) PhRMA points out that "Slovenian government pricing regulations have changed, on average, every 18 months." PhRMA has been working with the GoS to ensure the next pricing regulation changes are in-line with other EU countries pricing regulations. PhRMA lodged similar complaints about Slovenia in 2005, 2006, 2007 and 2008 (reftels B - E), but as in prior years, Post does not believe the complaints justify placing Slovenia on the watchlist. In 2008, Slovenia effectively dealt with one persistent PhRMA complaint from prior years - inefficient and slow judicial process due to court backlog. In 2008 they reduced the backlog of cases by 52%. Slovenia's continual improvements in the judicial field indicate a willingness to address identified issues and bring Slovenia into line with EU directives.

Conclusion

¶4. (SBU) In all other areas of IPR and data protection, Slovenia complies with international standards. Post's 2008 comments on related IPR issues (Reftel B) remain valid for ¶2009. Post recommends that Slovenia stay off the Special 301 Watch List in 2009.
FREDEN